

**REMARKS**

Claims 1-6, 8-11, 31-35, 37-44, 110-117, 119-136, 138 and 139 were pending in the Application prior to the outstanding Office Action. With this Amendment, claims 1-5, 8-11, 139 and 140 remain in the case.

The Examiner indicates that claims 7, 36, 118 and 137 are withdrawn from consideration. However, Applicants note that pursuant to a prior restriction requirement and Applicants' Response A filed 29 April 2003, claims 12-30 and 45-109 also stand as withdrawn.

**I. CLAIM OBJECTIONS**

The Examiner has objected to claims 8, 10 and 138 for informalities in that they are dependent upon withdrawn claims.

Claims 8 and 10 have been amended to depend from claims 1 and 4, respectively, neither of which have been withdrawn.

Claim 138 has been canceled.

Accordingly, it is believed that the claim objections have been overcome.

**II. ART REJECTIONS**

The Examiner has rejected claims 1, 2, 4-6, 10, 11, 31-35, 40-44, 110-117, 119-136, 138 and 139 under 35 U.S.C. §102(e) as being anticipated by Colon et al. (5,991,731). The Examiner also rejected claims 3 and 37-39 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Cimino, and rejected claims 8 and 9 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Breitfeld.

Of these rejections, Applicants consider the rejections of claims 6, 31-35, 37-44, 110-117, 119-136 and 138 to be moot since these claims have been canceled herein without prejudice. The only remaining rejections, therefore, are claims 1, 2, 4-5, 10, 11 and 139 as being anticipated by Colon, claim 3 as being unpatentable over Colon in view of Cimino, and claims 8 and 9 as being unpatentable over Colon in view of Breitfeld. Claim 1 is the only remaining independent claim, and Applicants will discuss this claim first.

**A. Independent Claim 1**

The Examiner rejected claim 1 as being anticipated by Colon. Colon teaches a centralized database and some centralized functional software for use during the operation of a clinical trial.

The Examiner cites Colon col. 6, lines 39-42 as teaching the "first patient eligibility criteria" called for in Applicants' claim, and cites Colon col. 6, line 39 - col. 7, line 10 as teaching the first plurality of workflow tasks called for in Applicants' claim.

Claim 1 has been amended to call for, among other things:

wherein the post-enrollment workflow tasks include at least one element of the group consisting of a post-enrollment instruction to have a specified test performed on the patient, and a post-enrollment instruction to have a specified CRF completed for the patient.

Colon does not indicate that either of these types of instructions be included in his database.

Accordingly, since Colon fails to teach an element called for in Applicants' claim, it cannot anticipate. Claim 1 therefore should be patentable.

**B. Dependent Claims 2, 4-5, 10, 11 and 139**

These claims all depend ultimately from independent claim 1 and therefore are believed to be patentable for at least the reasons set forth above with respect to independent claim 1. In addition, these claims each add their own limitations which, it is submitted, render them patentable in their own right.

Claim 4, for example, as amended calls for the "first plurality of workflow tasks" identified by the machine readable database of claim 1 to include specifically the post-enrollment instruction, mentioned in claim 1, to have a specified CRF completed for the patient. As already mentioned with respect to claim 1, Colon does not indicate that this type of instruction be included in his database.

Claim 5, as another example, as amended calls for the "first plurality of workflow tasks" identified by the machine readable database of claim 1 to include specifically the post-enrollment instruction, mentioned in claim 1, to have a specified test performed on the patient. As already mentioned with respect to claim 1, Colon does not indicate that this type of instruction be included in his database.

Accordingly, dependent claims 2, 4-5, 10, 11 and 139 are all believed to be patentable as well.

**C. Dependent Claim 3**

The Examiner rejected claim 3 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Cimino.

Claim 3 depends from independent claim 1 and therefore is believed to be patentable for at least the reasons set forth above with respect to independent claim 1. In addition, claim 3 adds its own limitations which, it is submitted, render the claim patentable in its own right.

Claim 3 calls for, among other things:

wherein said database identifies a term by reference to a controlled medical terminology database.

Thus the claim calls for the same database that identifies patient eligibility criteria for a clinical trial protocol also to identify post-enrollment workflow tasks to be performed during the operation of the clinical trial. By using a CMT in the clinical trial protocol database, greater unification can be achieved among the various stages of a clinical trial that were previously seen as widely disparate.

The Examiner cites pp. 154 and 162 of Cimino as teaching that "controlled medical terminologies (CMTs) are at the heart of most medical systems." But Cimino is speaking of a more common use of CMTs, to support "distributed cognition in patient care." Cimino, p. 161. As mentioned in Applicants' specification at p. 17, lines 7-8, CMTs were not originally intended for use in the field of clinical trial protocols. Cimino is no exception to this general understanding.

Cimino does not appear even to mention clinical trials, much less suggest that CMTs can be used in a database that identifies widely disparate features of a clinical trial protocol. The Examiner's citation to Cimino p. 161 as motivating such a combination is to no avail because there Cimino was speaking of patient care applications, not clinical trial protocols.

Accordingly, claim 3 is believed to be patentable in its own right.

**D. Dependent Claims 8 and 9**

The Examiner has rejected claims 8 and 9 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Breitfeld.

Claim 8 depends from claim 1 and should be patentable for the same reasons as claim 1. In addition, claim 8 calls for, among other things and as amended, "wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before an instruction to obtain informed consent." According to parent claim 1, the "first plurality of workflow tasks" referenced in claim 8 are to be identified in a machine readable database.

The Examiner cites Breitfeld as teaching the limitations of claim 8. Breitfeld teaches a system in which patient information can be entered, and an informed consent form can be printed for the patient to sign.

Breitfeld does not teach that any *instruction* to obtain the information or to obtain informed consent, be included in a database. Breitfeld's system may have a place where a user can *enter* the information, or a way for the user to have the informed consent form printed, but nothing in Breitfeld suggests that a database include an *instruction* to do these things.

Nor is the Examiner's cited motivation to combine compelling. The Examiner argues that that the motivation for combining Breitfeld with Colon would have been "so that eligible patients are informed of what will happen during the study." That may be a motivation to prevent patients from being enrolled in the study before they sign informed consent forms, but it does not provide any motivation to include an *instruction* in a clinical trial protocol *database* to obtain certain patient medical information before an *instruction* to obtain informed consent.

Similarly, claim 9 depends from claim 8 and should be patentable for the same reasons. Claim 9 further adds a limitation that first plurality of workflow tasks in the database includes a pre-enrollment *instruction* to obtain specified patient medical information *after* the instruction to obtain informed consent. Again, Breitfeld does not teach this feature and does not render claim 9 obvious.

It is respectfully submitted, therefore, that claims 8 and 9 should be patentable.

**II. CONCLUSION**

The references cited by the Examiner but not relied upon have been reviewed, but are not believed to render the claims unpatentable, either singly or in combination.

Claim 140 has been added to more particularly point out the invention.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

A three-month extension of time is hereby requested, and the appropriate fee is being submitted herewith for extending the time to respond up to and including 06 December 2006.

The Commissioner is hereby authorized to charge any fee determined to be due in connection with this communication, or credit any overpayment, to our Deposit Account No. 50-0869 (FSTK 1000-0).

Respectfully submitted,

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